

Applicants: Spiridigliozi et al.  
Serial No.: 10/643,315  
Filing Date: August 19, 2003  
Docket No.: 760-100 CIP/RCE  
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**REMARKS**

Claims 1 to 47 are pending in this application. Claims 16, 18, 34, 36, and 38 to 47 were previously withdrawn from consideration as being directed to non-elected species/invention. Claims 1 to 15, 17, 19 to 33, 35 and 37 remain pending.

Applicants thank the Examiner for the September 11, 2007 interview held between the Applicants' representative and the Examiner. Claims 1 and 19 have been amended to clarify the claims.

**I. Section 112 Rejection**

Claims 1 to 15, 17, 19 to 33, 35, and 37 have been rejected under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement.

In response, Applicants submit that, the clarifying amendments to claims 1 and 19 obviate this rejection. The amendments are supported by the specification at paragraph [0090]. Withdrawal of the Section 112 rejection is respectfully requested.

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## **II. Obviousness-Type Double Patenting Rejection**

Claims 1 to 15, 17, 19 to 33, 35 and 37 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 to 3 and 5 to 17 of co-pending Application Number 10/166, 842.

In response, Applicants have taken formal notice of this issue. Upon indication of allowable subject matter, Applicants will consider filing a terminal disclaimer to obviate this obviousness-type double patenting rejection over co-pending Application Number 10/166,842.

## **III. Section 103 Rejection**

Claims 1 to 15, 17, 19 to 33, 35 and 37 remain rejected under 35 USC §103 (a) as allegedly being unpatentable over the U.S. Pat. No. 4,850,999 to Planck (hereinafter "Planck '999") in view of the U.S. Pat. No. 6,264,684 to Banas (hereinafter "Banas '684"), and in further view of U.S. Pat. No. 5,628,788 to Pinchuk (hereinafter "Pinchuk '788"). Applicants respectfully traverse.

Planck '999 is cited for its disclosure of a composite made from a stent sandwiched between two layers of ePTFE and having a third outer layer of textile. The Examiner admits that Planck '999 fails to disclose a bonding agent. The Examiner then relies on Banas '684 for its disclosure of bonding agent and the application of a bonding agent to a graft having a plurality of longitudinally spaced crimps. The Examiner further combines Planck '999 and Banas '684 with

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Pinchuk '788, the later being used for its disclosure of a polyurethane bonding agent being applied in a dimethylacetamide solution.

Applicants respectfully traverse the Examiner's rejection on the basis that the claims, as amended, are distinguished over the prior art. Independent claims 1 and 19, as amended, clarify that a masked portion of the pleated layer is not secured by the bonding agent to the opposing layer, and thus facilitates unfolding and longitudinal lengthening of the implant.

Such combination of features is not disclosed in any of the prior art references either individually or in combination, and thus their combination does not render the present invention obvious. The Banas '684 reference, which the Examiner states as disclosing "crimps", actually discloses a polymer clad wire stent, the cladding being helically wrapped around a grant member. The polymer is clad completely around the surface of the wrapping wire and melted to join and seal the overlapping seams shown in figures 13 and 14. This is specifically recited in the Banas '684 disclosure, wherein it refers to these figures in column 10, lines 47 to 56 as follows:

*"Finally, an alternative embodiment of a shape memory alloy supported intraluminal graft 80 is depicted in figures 13 and 14. The inventive shape memory alloy supported intraluminal graft 80 may be formed by helically wrapping a length of polymer clad 84 shape memory alloy wire 86 about a supporting winding mandrel, such that the polymer*

*cladding 84 has overlapping regions 88 which form seams.*

*The resulting assembly is then heated above the melt point  
of the polymer cladding 84 to join and seal the overlapping  
regions 88 to one another." (emphasis added)*

Banas '684 clearly states that the resulting assembly is melted to join and seal the overlapping regions 88 to one another. Thus, the Banas '684 disclosure makes it clear that the overlapping regions are sealed and melted together to form joined seams. This is distinct from the present invention wherein the masked portion is not secured to the textile material by the bonding agent in order to permit unfolding of the pleat and longitudinal lengthening of the material. Therefore, Banas '684 fails to teach or suggest pleated folds which form a masked portion which does not get bonded to the underlying layer and thus can unfold and lengthen. In fact, Banas '684 clearly directs a person of ordinary skill in the art away from the inventive features provided in the claims as amended.

Furthermore, the present invention, as claimed in claims 1 and 9, also provides for another layer formed of textile material disposed over the pleated layer. The device according to Banas '684 discloses a "self-expanding stent-graft device" with the top layer being a polymer clad stent that radially self-expands. Banas '684 provides no teaching or suggestion to provide a second layer formed of textile material over the polymer clad stents, and moreover such an additional top layer may encumber the polymer clad stents from expanding radially. Therefore,

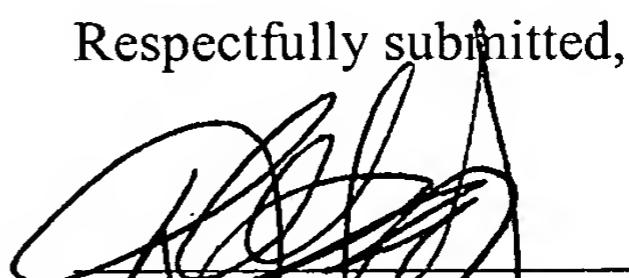
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Banas '684 cannot properly be combined with Planck '999 and Pinchuk '788 to arrive at the present invention.

In conclusion, amended claims 1 and 19 are not be obvious in view of the above references, since the references taken for their teachings as a whole, are devoid of any teaching or guidance which would lead one of ordinary skill in the art to the invention. Additionally, claims 2 to 15 depend on claim 1 and claims 20 to 33, 35, and 37 depend on claim 19. Since the dependent claims include the combination of features from the independent claims, the prior art as a whole also fails to teach or suggest the combination of features included in these claims as well.

Should the Examiner determine that issues remain that have not been resolved by this response, the Examiner is requested to contact Applicants' representative at the number listed below.

Respectfully submitted,



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